

Patient briefing



Alert

29 July 2004

**This is a summary
of the alert issued
to the NHS**

Ensuring the safety of patients using oral methotrexate

What is oral methotrexate?

Oral methotrexate is a medicine given to patients who have moderate or severe rheumatoid arthritis - this includes patients suffering from juvenile arthritis and patients with severe uncontrolled psoriasis which hasn't responded to normal treatment. 'Oral' simply means that it is taken via the mouth. 50,000 prescriptions for oral methotrexate are issued in the NHS each year.

Note: In some cases the medicine is also prescribed to patients for leukaemia by a hospital oncology unit. This summary does not apply to these patients as they are closely monitored by hospital staff, and will receive different doses of the medicine.

What is the safety risk to patients who take oral methotrexate?

Oral methotrexate is taken by patients in their own home and is normally safe as long as it is used properly. Proper use means that the medicine is only taken weekly, that the patient fully understands how and when it should be taken and that they regularly receive check-ups to make sure that the medicine is working correctly.

The National Patient Safety Agency (NPSA) has found, however, that serious problems can occur if the proper treatment routine is not followed. Over a ten year period in England 25 patients died, with a further 26 suffering serious harm, because the medicine had either not been used or monitored properly.

How do mistakes happen?

The most common mistakes in the medicine's use are: that the patient does not understand the correct dosage, perhaps because of lost or unclear instructions; that the medicine is accidentally taken more frequently because it has been confused with other medication; that the patient is not fully aware of the warning signs associated with the medicine not working properly; that the wrong dose is given because of unclear packaging; and that confusion exists between healthcare providers as to who is responsible for the monitoring of patients.



What is the National Patient Safety Agency doing to solve the problem?

Although serious harm and death is extremely rare in the use of oral methotrexate, the NPSA is working to ensure that patients receive the highest quality and safest possible care. The NPSA is:

- Sending a patient safety alert to all medical directors in England and Wales highlighting the problems with oral methotrexate and advising on how they can act to ensure that the safety of patients is protected.
- Working with the pharmaceutical industry to develop safer, patient-friendly packaging. Pfizer and Mayne Pharma have already changed the shape of the 10mg tablet to distinguish it from the 2.5mg tablet.
- Promoting guidelines and recommended content for patient information about oral methotrexate.

What should I do if I am concerned about taking oral methotrexate?

You should immediately seek medical advice from your pharmacist, GP or hospital doctor - but it is important that you do not stop taking the medicine before doing so.

More information

The full patient safety alert and patient information guidelines are available from the NPSA website at: www.npsa.nhs.uk/advice

The National Patient Safety Agency (NPSA) was established in July 2001 to improve the safety of NHS patients by promoting a culture of reporting and learning from patient safety problems.